

November 6, 2003

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Office of Nutritional Products, Labeling & Dietary Supplements, HFS 810 Center for Food Safety and Applied Nutrition Food and Drug Administration 5100 Paint Branch Parkway College Park, MD 20740



RE: Label Claims/Disclaimers

Dear Sir or Madam:

This letter is to notify you that the following product is Manufactured, Packed, and/or Distributed by PhytoPharmica (a Division of Integrative Therapeutics, Inc.), at 825 Challenger Drive, Green Bay, Wisconsin 54311 has a label that contains a statement provided by section 403(r)(6) of the Federal Food, Drug and Cosmetic Act. PhytoPharmica wishes to take advantage of the exemption to section 201(g)(1)(C) of the act and comply with section 403(r)(6) of the act. These claims are not necessarily for a product we currently market or plan to market in the immediate future, and may be exploratory in nature.

PRODUCT NAME	<u>STATEMENT</u>	INGREDIENT(S) TO WHICH THE CLAIM REFERS
Clinical Nutrients <sup>™</sup> for 45-Plus Women	With just three simple steps Easy Answers Stage 3 gives you a full range of nutritional support, keeps those bones healthy and strong and controls menopausal symptoms.*	Vitamin A, Vitamin C, Vitamin D, Vitamin E, Vitamin K, Thiamin, Riboflavin, Niacin, Vitamin B6, Folic Acid, Vitamin B12, Biotin, Pantothenic Acid, Calcium, Phosphorus, Iodine, Magnesium, Zinc, Selenium, Copper, Manganese, Chromium, Molybdenum, Sodium, Potassium, Choline Bitartrate, Ginger Rhizome Extract, Black Tea Leaf Extract, Cherry Fruit Extract, Green Tea Leaf Extract, Inositol, Soy, Cranberry Fruit Extract, Betaine HCI, Grape Seed Extract, Bromelain, Papain, Bilberry Fruit Extract, Pepsin, Lipase, Boron, Lutein, Silicon, Vanadium, Zeaxanthin

978 0162 LET /3334

825 CHALLENGER DRIVE GREEN BAY, WI 54311-8328 920-469-9099 TOLL FREE 800-553-2370 FAX 920-469-4418 FAX TOLL FREE 888-311-5657 WWW.PHYTOPHARMICA.COM I certify that the information contained in this notice is complete and accurate and that PhytoPharmica, (a Division of Integrative Therapeutics, Inc.), has substantiation that the statements are truthful and not misleading.

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•	Robert C. Doster Senior Vice President of Scientific Affairs	
Date:	11/6/03	

If you have any questions, please contact Robert Doster, Senior Vice President of Scientific Affairs, at (920) 406-3608.

Sincerely,

Michael P. Devereux Chief Financial Officer